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09/825,246	04/02/2001	Sharat Singh	0225-0033.20	4459

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EXAMINER

TUNG, JOYCE

ART UNIT	PAPER NUMBER
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1656

DATE MAILED: 01/30/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/825,246

Applicant(s)

Singh et al.

Examiner

Joyce Tung

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 6 20) ☐ Other:

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DETAILED ACTION

Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321© may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 1-7 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3, 5-7, and 9-10 of copending Application No. 09/824,905. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims 1-7 are drawn to a set of electrophoretic tag probes which has the same feature as the set of electrophoretic tag probe claimed in the kit of claims 1-3, 5-7 and 9-10. Thus, it would have been prima facie obvious to claim the set of electrophoretic tag probe which has the same feature as the set of electrophoretic tag probe claimed in the kit of claims 1-3, 5-7 and 9-10.

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This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

3. Claims 1-15 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-19 of copending Application No. 09/825,245. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims 1-15 are drawn to a set of electrophoretic tag probes which has the same feature as the set of electrophoretic tag probe claimed in the composition of claims 1-19. It would have been prima facies obvious to claim the set of electrophoretic tag probes because the set of electrophoretic tag probes has the same feature as the set of electrophoretic tag probe claimed in the composition of claims 1-19 of copending Application No. 09/825,245.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

4. Claims 1-5 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4 of copending Application No. 09/824,851, claims 1-4 of copending Application No. 09/824,861. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims 1-5 are drawn to a set of electrophoretic tag probes which has the same feature as the set of electrophoretic tag probe in the kit of claims 1-4 of copending Application No. 09/824,851.

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The set of electrophoretic tag probes of instant claims 1-5 also has the same feature as the set of electrophoretic tag probe in the composition of copending Application No. 09/824,861. It would have been prima facie obvious to claim the set of electrophoretic tag probes because the set of electrophoretic tag probes of the instant claims 1-5 has the same feature as the set of electrophoretic tag probes in the kit of 09/824,851 or the composition of 09/824,861.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Objections

5. Claims 1-15 are objected to because of the following informalities: U₁ in claim 1 might be typographic error. Appropriate correction is required.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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- a. Claims 1-15 are vague and indefinite because the subscript of $B_{i,i+1}$ is unclear what is the number for the linkage $B_{i,i+1}$. In addition, it is unclear what is the number for "j".
- b. Claim 6 is vague and indefinite because the phrase "each M_j has a unique charge/mass ratio by virtue of variations in mass, but not charge". Does the phrase meant that the charge is constant, but the mass is various.
- c. Claim 7 is vague and indefinite because the phrase "each M_j has a unique charge/mass ratio by virtue of changes in both mass and charge". Does the phrase meant that the charge and mass are various.
- d. Claims 1-15 are vague and indefinite because the language "N is a nucleotide joined to U_1 in T_j through a nuclease-cleavable bond" and the language "the e-tag reporter (D, M_j) - N does not itself contain nuclease-cleavable bonds". It is unclear whether or not the phrases are conflicting. It is suggested to clarify uncertainty.
- e. Claims 6-7 are vague and indefinite because it is unclear how the language "a unique charge/mass ratio" and "a unique mass/charge" is defined in the specification.
- f. Claims 1-15 are vague and indefinite because it is unclear what is the definition of the language "mobility modifier". Since each molecule has a charge and mass, each molecule has the property of the mobility. It is suggested to clarify the definition.
- f. Claim 4 is vague and indefinite because the language "the nuclease-resistant bond(s)" has no antecedent basis

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Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1-3, and 10-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Grossman et al. (5,470,705).

Grossman et al. disclose a probe comprising the feature of the e-tag probe as claimed in claim 1 and its dependent claims 2-3 and 10-15. The probe of Grossman et al. is captured (See column 20, lines 47-49). This is inherent that there is a capture agent bound to the probe. The probe includes a binding polymer, a polymer chain which imparts to that probe, a distinctive ratio of charge/translational frictional drag and a reporter attached to the binding polymer (See column 20, lines 52-57). The probe is also cleavable with nuclease at the 5' end subunits from the probe and the probe releases a labeled probe composed of base, reporter and polymer chain (See column 19, lines 62-67 to column 20, lines 1-25). The released probe is the same as the form (D, M_j) - N structurally. Thus, it is inherent that in claim 1 (a)(iv) the e-tag reporter (D, M_j) - N does not itself contain nuclease-cleavable bonds. The binding polymer is an oligonucleotide including at least 10-20 bases allowing hybridization to the target polynucleotide (See column 6, lines 66-67 and column 7, lines 1-10). Other binding polymers are analogs of polynucleotides, such as deoxynucleotides with thiophosphodiester linkage (See column 7, lines 11-19). The polymer

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chain has a ratio of charge/translational frictional drag which is evidenced by a distinctive electrophoretic mobility in a non-sieving matrix (See column 7, lines 50-64). The label refers to a fluorophore or chromophore (See column 6, lines 39-44). The feature of Grossman et al.'s probe anticipate the features of the claimed e-tag probe.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

11. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Grossman et al. (5,470,705), as applied to claims 1-3, and 10-15 above, and further in view of Babon et al. (5,851,770).

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The teachings of Grossman et al. are set forth in section 9 above. Grossman et al. do not disclose that the probe contains a capture ligand as indicated in claim 5.

Babon et al. disclose a method for detecting one or more mismatches between a first and second nucleic acid in which the heteroduplex formed between the first and second nucleic acid sequence is biotinylated and captured by binding to streptavidin-magnetic beads (See column 7, lines 53-66). The capture ligand and capture agent includes antigen/antibody or DNA binding protein and its DNA binding site (See column 18, lines 13-24). Thus, it would have been prima facie obvious to one of ordinary skill in the art at the time of the instant invention to modify the probe of Grossman et al., wherein the capture ligand/agent are attached to the oligonucleotide probe as taught by Babon et al.. The ordinary skill in the art would have been motivated to make this invention because directly capturing the probe to a solid support is easy to wash away the unbound probe which increases the accuracy of the method instead of capturing the probe through the immobilized target sequence as disclosed by Grossman et al.

12 Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Grossman et al. (5,470,705) as applied to claims 1-3 and 10-15 above, and further in view of Huie et al. (5,470,967).

The teachings of Grossman et al. are set forth in section 9 above. Grossman et al. do not disclose that the probe contains phosphodiester bond linkage and nuclease resistant bonds as claimed in claim 4.

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Huie et al. disclose phosphodiester linkage in oligonucleotide analogs (See column 3, lines 59-62) and phosphorothioate diester shows increased resistance to nuclease (See column 3, lines 59-67). Thus, it would have been prima facie obvious to one of ordinary skill in the art at the time of the instant invention to use phosphodiester linkage as indicated by Huie et al. in the oligonucleotide probe of Grossman et al. because the use of modified linkage within the oligonucleotide makes them nuclease resistant (See column 3, lines 63-67).

13. Any inquiries concerning this communication or earlier communications from the examiner should be directed to Joyce Tung whose telephone number is (703) 305-7112. The examiner can normally be reached on Monday-Friday from 8:00 AM-4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached at (703) 308-1119 on Monday-Friday from 10:00 AM-6:00 PM.

Any inquiries of a general nature or relating to the status of this application should be directed to the Chemical/Matrix receptionist whose telephone number is (703) 308-0196.

14. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Art Unit 1656 via the PTO Fax Center located in Crystal Mall 1 using (703) 305-3014 or 308-4242. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).

Joyce Tung

EGGERTON A. CAMPBELL
PRIMARY EXAMINER

January 25, 2002

